Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The Effects of Family-Based Dignity Intervention and Expressive Writing Intervention on Grief of Family Caregivers of Clients With Cancer: An Embedded Mixed Methods Study

Protocol summary

Study aim

The Effect of a Mixed Methods Study on Family-based Dignity Intervention (FDI) and Expressive Writing (EW) on Anticipatory Grief (AG) in Family Caregivers (FCg) of cancer patients.

Design

A RCT will be done. FCg will be randomly assigned to one of the four groups: FDI , EW , Combined FDI and EW and controls. After the random allocation, sessions related to the interventions will take place . Before the session and one week and two weeks after the interventions, AG will be assessed by a AG scale

Settings and conduct

In this study, we will include FCg of dying cancer patients who refer to oncology and palliative care center affiliated to the Iran University of Medical Sciences, Tehran, Iran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: FCg who are the first-degree relatives of cancer patients and have the most responsibility for caregiving of them during the last 3 months. Non-inclusion criteria: FCg who have a history of psychological disorders and those who have a history of death among their first-degree relatives.

Intervention groups

FDI A 60-90-minute dignity therapy interview session will take place for each FCg . The responses to these questions will be audio-recorded and then, will be transcribed verbatim in a manuscript . A copy of the manuscript will be delivered to caregivers. EW : They will be also told to write about their experiences of caregiving . After one week opportunity for EW the manuscript of caregivers will be received. Combined FDI and EW: At first, the session related to FDI will be hold and after that, training on EW will be delivered to FCg. After one week from the last session, the manuscript of caregivers will be received. Control group: FCg in the control group as well as those in the intervention groups will receive routine cares such as family counseling and meaning therapy.

Main outcome variables

Anticipatory Grief

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210111050010N1**
Registration date: **2021-02-06, 1399/11/18**
Registration timing: **prospective**

Last update: **2021-02-06, 1399/11/18**
Update count: **0**

Registration date

2021-02-06, 1399/11/18

Registrant information

Name

masoud Rezaei

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2022-02-20, 1400/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effects of Family-Based Dignity Intervention and Expressive Writing Intervention on Grief of Family Caregivers of Clients With Cancer: An Embedded Mixed Methods Study

Public title

The Effects of Family-Based Dignity Intervention and Expressive Writing on Grief of Family Caregivers of Clients With Cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

having over 18 year 's old Not having of known psychological disorders in family caregivers of cancer patients Not having a history of death in close relatives last 6 month

Exclusion criteria:

Caregivers who have a history of psychological disorders Those who have a history of death among their first-degree relatives. Those who have an experience of psychological interventions

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **200**

Randomization (investigator's opinion)

Randomized

Randomization description

After recruiting 200 family caregivers of dying cancer patients according to inclusion criteria, they will be randomly assigned to one of the four groups: family-based dignity intervention (group 1), expressive writing intervention (group 2), combined family-based dignity intervention and expressive writing (group 3), and controls (group 4). Allocation concealment will be done using the blocked randomization method. For this, we will use six blocks with the sizes of 4 (A: group 1, B: group 2, C: group 3, and D: group 4) that the order of the letters in the six block will be different (e.g. ABCD, ACDB, and etc.). Then, a code ranging between 1 and 6 will be assigned to each block. For allocating each four caregivers, at first, we will randomly select one of the six blocks using a 6-sided dice, and then, caregivers will be assigned to the four intervention group according to the order of letters in the selected block. Until the all groups become complete, the random allocation will continue.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran National Committee for Ethics in Biomedical Research

Street address

School of Nursing & Midwifery, Rashid Yasemi st., Valiasr St., Tehran, 1996713883, IRAN

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Province

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Postal code

۱۹۹۶۷۱۳۸۸۳

Approval date

2021-01-11, 1399/10/22

Ethics committee reference number

IR.IUMS.REC.1399.1097

Health conditions studied

1

Description of health condition studied

Our community for study is healthy caregivers

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Anticipatory Grief

Timepoint

pretest- one week and two week after intervention

Method of measurement

Licertic scale

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group :In Family-based dignity intervention caregivers will received family-based dignity intervention according to Ho et al. protocol as well as routine interventions including family counseling and hope and meaning therapy. For the dignity intervention, a 60-90-minute intervention interview session will take place for each caregiver in a private room in the palliative care center. In this session, caregivers will be asked to answer 12 open-ended questions related to the Ho et al. protocol. The questions focus on eliciting caregivers' experiences of living with a cancer patient before and after the diagnosis of cancer. Also, these questions will help caregivers to review the beautiful memories of living with a cancer patient and express their hopes, wishes, and desired expectations. The responses to these questions will be audio-recorded and then, will be transcribed verbatim in a manuscript for each caregiver. The manuscript will be checked with caregivers and, if needed, corrections will be done. A copy of the manuscript will be delivered to caregivers. One week after the baseline assessment, anticipatory grief will be assessed (one week after T1 or T2). Two weeks after the baseline assessment, the anticipatory grief will be re-assessed.

Category

Other

2

Description

The Second intervention group: After assessing baseline anticipatory grief, caregivers will be asked to write about their positive and negative experiences during caregiving cancer patients. This intervention will be done based on the Pennebaker method. Before the intervention, caregivers will be instructed by a trained researcher in order to do this writing. The researcher will receive training on expressive writing by participating in a writing art workshop. Caregivers in this group will be asked to write about a prompt, and they will be instructed to ''really let go and explore their very deepest emotions and thoughts". They will be also told to write about either negative or positive family memories and describe their experiences of caregiving in the present and past time. This writing should be done three times (in a week) lasting 20 minutes. In that week, the researcher will remind the writing process using a phone call. They are also assured that they do not need to worry about sentence structure or grammar when writing. After one week opportunity for expressive writing, the manuscript of caregivers will be received. After the expressive writing, anticipatory grief will be assessed (one week after T1). Also, we will assess anticipatory grief two weeks after the baseline assessment (two weeks after T1).

Category

Other

3

Description

The third intervention group: caregivers will received both interventions mentioned in the previous paragraphs. At first, a 60-90-minute intervention interview session about family-based dignity intervention will take place for each caregiver in a private room in the palliative care center. After the interview, caregivers will be asked to write about their positive and negative experiences during caregiving cancer patients three times, lasting 20 minutes, in a week. After one week opportunity for expressive writing, the manuscript of caregivers will be received. One week after the expressive writing and dignity intervention, anticipatory grief will be assessed (one week after T1). Also, we will assess anticipatory grief two weeks after the baseline assessment (two weeks after T1).

Category

Other

4

Description

Control group : Caregivers will be received family counseling and hope and meaning therapy. The other 3 group will also receive the same intervention administered for group 4. Anticipatory grief will be assessed in the same times as mentioned for other intervention groups. In total, the duration of this study from participants entry to the last assessment will last four weeks.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Firoozgar hospital

Full name of responsible person

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Sponsors / Funding sources

1

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Name of organization / entity

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Full name of responsible person

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Iran University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Public

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Masoud Rezaei

Position
Master of science

Latest degree
Master

Other areas of specialty/work
Nursery

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available

Title and more details about the data/document

study outcomes by maintaining anonymity of participants

When the data will become available and for how long

starting information accessibility from 2022

To whom data/document is available

university researchers and healthcare workers and people

Under which criteria data/document could be used

Using the results of the study is permitted by regard the right of citations .

From where data/document is obtainable

To chief author in Iran faculty of nursing and midwifery

What processes are involved for a request to access data/document

Communicate with writers through email

Comments